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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/008,243	11/07/2001	Kevin Kelly Covey	1023-015US01	8259

28863 7590 02/25/2004  
SHUMAKER & SIEFFERT, P. A.  
8425 SEASONS PARKWAY  
SUITE 105  
ST. PAUL, MN 55125

EXAMINER

MANUEL, GEORGE C

ART UNIT PAPER NUMBER

3762

DATE MAILED: 02/25/2004

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/008,243

Applicant(s)

COVEY ET AL.

Examiner

George Manuel

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 27 February 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-59 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-59 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 2/27/02.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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## DETAILED ACTION

1. *Claim Rejections - 35 U.S.C. § 102*

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

3. Claims 1-4, 6, 8, 9 and 11-14 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Kroll '690.

Kroll discloses a pouch 62. The examiner is interpreting the pouch to contain an electrode, i.e., a surrogate electrode 64 is connected to a tab 66 of pouch 162. See claim 9.

Figure 6 shows an anchor comprising a tab for mating non-permanent attachment to an ICD.

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4. Claims 1, 5, 17, 18, 28-31, 34, 53, 55 and 56 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Walters et al '640.

Walters et al disclose a handle comprising end 14 and a notch comprising the torn portion shown in Fig. 1.

5. Claims 1-4, 6, 10, 17-20, 28-31, 53, 55 and 56 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Faller et al '709.

Faller et al disclose a notch comprising tear line 32.

6. Claims 1, 6 and 7 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Kawaguchi '645.

Kroll discloses a medical device comprising a conductive solution, pouches 12 and 14 on electrodes 16 and 18, and a substantially cylindrical anchor comprising portion 32.

7. Claim 35 is rejected under 35 U.S.C. 102(e) as being clearly anticipated by Nova et al '885.

***Claim Rejections - 35 U.S.C. § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1, 16, 17, 26, 27, 28, 33, 35-38, 40-43, 45-53 and 56-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walters et al '640 in view of Bishay et al '598.

Walters et al show all of the claimed features except for instructive pictures on the electrodes to illustrate placement of the electrodes on the patient.

Bishay et al teach using images on electrodes to assist an operator in determining placement of electrodes on a patient. One of ordinary skill in the art would have found it an obvious modification of the electrode imaging to image the packaging material instead of, or in addition to, the electrode imaging because the imaging is disclosed as being visible through the packaging material in Fig. 1.

One of ordinary skill in the art would have found it obvious to combine the teaching of Bishay et al with the electrodes of Walters et al for illustrating placement of the electrodes because the teaching of Bishay et al applies to defibrillation electrodes which are the same type of electrodes disclosed in Walters et al and because time is critical for fast electrode placement and a visual display on the electrode minimizes the time needed for an operator to place the electrodes on a patient.

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Regarding claims 45, 49 and 50, one of ordinary skill in the art would have found it obvious to use distinct coloring because Bishay et al teach a combination of color usage and bolding may be employed to enhance the readability of the images.

9. Claims 1, 15, 17, 23, 24, 25, 28, 32, 35, 39, 41, 43, 44, 53 and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walters et al '640 in view of Bishay et al '598 and further in view of Nova et al '070.

Claims 1, 17, 28, 35, 41, 43 and 53 are rejected as being unpatentable over Walters et al in view of Bishay et al as stated above.

One of ordinary skill in the art would have further found it obvious to provide instructions for opening the package disclosed in Walters et al in view of the teaching in Nova et al that an additional visual instruction may be displayed for electrode package opening action.

The teaching of Nova et al applies to a similar package of defibrillator electrodes and therefore applies to the package arrangement of Walters et al in view of Bishay et al.

10. Claims 17, 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Freeman et al '157.

Freeman et al show all of the claimed features except for a ring shaped handle.

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One of ordinary skill in the art would have found it obvious to modify the tab 40 to have a ring shape because it is well known in the art of packaging materials to use a ring shape so a person opening the package can insert a finger or use the index finger and thumb to grasp the ring shaped tab to assist in opening.

***Conclusion***

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to George Manuel whose telephone number is (703) 308-2118. The examiner can normally be reached on Mon.- Fri., 9:00-5:00.

The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306 for regular communications and for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1148.

  
George Manuel  
Primary Examiner  
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February 19, 2004